

An Eastern Shore Dialysis Center Illness Cluster Virginia Department of Health Situation Summary – March 26, 2007

What has happened with the dialysis center?

On March 2, 2007, a hemodialysis center on the Eastern Shore contacted the Virginia Department of Health (VDH). This was to notify VDH about a cluster of illness in patients who attend the center. Several people in the cluster were hospitalized; one person died. The facility voluntarily closed to start an investigation of the problem.

The illness seemed to be due to hemolytic anemia (destruction of red blood cells). The dialysis center's water purification system was most likely the source of the problem. However, the precise cause remains unknown. Unfortunately, it is unlikely that the final cause will ever be known for sure.

Have similar things happened at other centers?

The scientific literature has reports of outbreaks of hemolytic anemia in dialysis patients at other centers. There have been many causes identified in these outbreaks. These have included water contamination with such things as chloramines, hydrogen peroxide, formaldehyde, or heavy metals like copper, in combination with a problem with the purification system.

The particular dialysis center on the Eastern Shore does not report ever having had a similar problem. The facility is also not aware of any similar problem in their associated facilities. As a result, it is believed that this was an isolated event.

How many individuals were affected?

Currently, it is thought that no more than four or five individuals developed illness sufficiently severe to require medical evaluation. The number of individuals who were exposed or only mildly affected cannot be determined. However, long-term red blood cell damage is not expected. Exposed individuals should recover once the exposure has ended.

What's being done to investigate? Who is involved?

The dialysis center, as well as local health department staff, the VDH Office of Licensure and Certification, the VDH Office of Epidemiology, and experts from the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS), have collaborated to try to identify the cause of the illness. The investigation has involved careful review of the facility, procedures/protocols, staff, and patient information.

How long has the health department been involved? What are the roles?

The local and state health departments have been involved from their notification on March 2, 2007. There have been two separate, but collaborative, investigations. The Office of Epidemiology has been involved in trying to determine possible causes or risk factors in patients. The Office of Licensure and Certification has been working to identify procedural or technical problems related to the facility.

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Why is this investigation taking so long?

Hemodialysis is a complex process. Hemodialysis patients often have complex medical histories that need to be considered. In addition, hemolytic anemia can have many causes. Finally, comparable information on every patient and case is not available. Therefore, the complexity of the situation combined with the relative lack of data has meant a longer and more difficult investigation.

When will all the investigations be complete?

The bulk of the investigations have been completed. Additional work remains to further analyze some data. However, it is not expected that these studies will significantly affect the findings.

Can you guarantee this won't happen again? What is being done to ensure that this doesn't happen again?

Without being able to determine exactly what happened, it is difficult to guarantee that it couldn't happen again. The dialysis center and the VDH Office of Licensure and Certification have fully reviewed the facility's procedures, protocols, and equipment. As a result of these investigations, the dialysis center staff has developed and submitted plans to VDH to meet all appropriate safety standards. In addition, some critical equipment has been updated to further reduce the risk. Finally, facility staff will be carefully evaluating patients in order to detect any health problems early.

The VDH Office of Licensure and Certification has approved these plans. As a result, on Monday March 26, 2007, the facility was able to re-open. The VDH Office of Licensure and Certification will re-inspect the facility in the near future to follow-up on the facility's progress.

VDH understands the difficulty that this situation created. The additional travel time to other facilities for treatment significantly increased the burden on the patients and families. However, every effort was made to ensure that the facility could safely open as soon as possible. VDH and the dialysis center staff appreciate the patience and understanding of the patients and their families.

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